



## STAFF REPORT ACTION REQUIRED

### Patent Protections and Government Use Overrides

<b>Date:</b>	March 9, 2009
<b>To:</b>	Executive Committee
<b>From:</b>	City Solicitor
<b>Wards:</b>	All
<b>Reference Number:</b>	

#### **SUMMARY**

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The purpose of this report is to advise the Executive Committee of the general patent protections granted to patentees under the federal *Patent Act* and to highlight exceptions to these patent protections.

The Commissioner of Patents may authorize the use of a patented invention by the federal government in cases of national emergency or extreme urgency or where the use for which the authorization is sought is a public non-commercial use.

#### **RECOMMENDATIONS**

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The City Solicitor recommends City Council receive this report for information.

#### **FINANCIAL IMPACT**

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While this report may not have any direct financial impact, possible actions discussed in this report relating to overriding drug patent protection may have some impact on the financial implications related to stockpiling Tamiflu in the very long term.

#### **DECISION HISTORY**

At its meeting April 7, 2008, the Executive Committee considered the report (March 19<sup>th</sup>, 2008) from the City Manager, Medical Officer of Health and the Deputy City Manager and the Chief Financial Officer concerning stockpiling requirements for pandemic influenza preparedness. The Executive Committee requested the City Solicitor to submit a report on a possible request to the Federal Government to enact legislation to override

drug patent protection in the event of a widespread pandemic and to seek international co-operation with other countries through the World Health Organization.

<http://www.toronto.ca/legdocs/mmis/2008/ex/bgrd/backgroundfile-11754.pdf>  
<http://www.toronto.ca/legdocs/mmis/2008/ex/bgrd/backgroundfile-11217.pdf>

## **ISSUE BACKGROUND**

City Council is taking steps to finalize its influenza pandemic preparedness plans, including plans for the purchase of the antiviral medication Oseltamivir (Tamiflu). Tamiflu is only manufactured and supplied by the patent holder, Hoffman-La Roche. The Canadian patent will expire on May 7, 2019. Currently, a less costly generic equivalent of Tamiflu is not available.

## **COMMENTS**

### **Patent Protections Generally**

Patent law in Canada is governed by the *Patent Act*. A patent grants patent rights in an invention to a patentee for a term of 20 years if an application for a patent was filed on or after October 1, 1989. In exchange for an exclusive right to make, use and sell the invention, the patentee must disclose how the invention is made. The *Patent Act* is binding on the Government of Canada and provincial governments.

### **Government Use Override and limits on patent exclusivity**

Prior to 1994 the federal and provincial governments were able to use the patent of patentees without applying for the right to do so, provided the patentee was compensated appropriately. However, both the North America Free Trade Agreement (NAFTA) and the Trade Related Aspects of Intellectual Property Rights (TRIPS), an annex to the World Trade Organization Agreement, relate, in part, to intellectual property rights, including patent protection. All member countries (of which Canada is one) have agreed that their laws will conform to these agreements. The federal *Patent Act* was amended to conform with these international treaties. As a result, the Canadian and provincial governments' prior unfettered rights with respect to the use of patents have been restricted.

Under existing patent law, the Canadian government or a provincial government may apply to the Commissioner of Patents to use a patented invention. The Commissioner may authorize the use on certain terms. Those terms are settled in accordance with the following principles: the scope and duration of the use is limited, the authorized use is non-exclusive and the use is predominantly for the domestic market. If the use is authorized by the Commissioner the authorized user must adequately remunerate the patentee. The applicant must also demonstrate that it has made reasonable efforts to obtain authorization from the patentee to use the patent, on reasonable commercial grounds, and that these efforts were unsuccessful.

The requirement to make reasonable efforts to reach an agreement with the patentee does not apply in cases of national emergency or extreme urgency or where authorization for use of the patent is sought for a public non-commercial use.

One can also allege that a patentee has abused the exclusive rights it has been granted under the *Patent Act* provided three years has expired since the patent was granted. Exclusive patent rights shall be deemed to have been abused in a number of circumstances, including circumstances where the demand for the patented article in Canada is not being met to an adequate extent and on reasonable terms. The Attorney General or any interested person may apply to the Commissioner of Patents alleging there has been an abuse of the patent and seek relief from the Commissioner for the abuse. If an applicant alleges the patentee has failed to meet the demand for the product in Canada, the applicant must first approach the patentee and request a license. If the request is denied the Commissioner of Patents may order the grant of a licence to the applicant. These proceedings are infrequent; they are usually lengthy, expensive and have a low success rate.

## **Historic Use of the Government Use Override**

Historically, reliance on the government use override provisions in the *Patent Act* has been limited to supporting war efforts, specifically using patents for munitions and defence supplies. However, in 2001, at the time of the Anthrax scares in the United States, the federal government set out to secure an adequate supply of Ciprofloxacin, the antibiotic predominantly used for the treatment of anthrax. The Canadian government entered into an agreement with a manufacturer of generic drugs to manufacture an adequate supply of the antibiotic Ciprofloxacin. However, it did so without first making an application to the Commissioner of Patents. Although the actions of the government were controversial in this case, resulting in a negotiated settlement among the parties, it illustrates how the government override provisions in the *Patent Act* might be relied upon to secure an adequate supply of therapeutic drugs, such as Tamiflu.

## **Patent laws and Tamiflu**

Canadian patent laws are inextricably linked to international agreements requiring members of the World Trade Organization to adopt intellectual property laws that conform with these agreements. Therefore, requesting the federal government to amend existing patent legislation is not recommended. Similarly, seeking international cooperation with other countries to override patent restrictions is likely to be unsuccessful.

However, should it wish to do so, City Council could request the federal government to approach Hoffman La-Roche for authorization to use the patent for Tamiflu. Alternatively, and relying on the provisions in the *Patent Act* that authorizes it to do so, City Council could request the federal government to apply to the Commissioner of Patents for permission to use the patent for Tamiflu, on the grounds of national emergency/extreme urgency or public non-commercial use at the appropriate time.

In the further alternative if there is reason to believe that Hoffman-La Roche is unable to meet the demand for Tamiflu in Canada the Attorney General of Canada, on behalf of the federal government, could apply to the Commissioner of Patents for relief. The relief could be in the form of a compulsory license granted to someone other than the patentee, a process which could be lengthy and expensive.

## **CONTACT**

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## **SIGNATURE**

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